

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

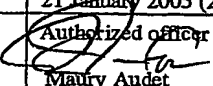
(PCT Article 36 and Rule 70)

REC'D 18 FEB 2005

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05 JUL 2005

Applicant's or agent's file reference <b>LA-7353-101.PC</b>	<b>FOR FURTHER ACTION</b>		See Form PCT/IPEA/416																								
International application No. <b>PCT/US04/01468</b>	International filing date (day/month/year) <b>21 January 2004 (21.01.2004)</b>	Priority date (day/month/year) <b>21 January 2003 (21.01.2003)</b>																									
International Patent Classification (IPC) or national classification and IPC <b>IPC(7): A61K 38/00 and US Cl.: 514/12</b>																											
Applicant <b>GENERBON BIOPHARMACEUTICALS LLC</b>																											
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p style="margin-left: 20px;">a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of ___ sheets, as follows:</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p style="margin-left: 20px;">b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> <p>4. This report contains indications relating to the following items:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 10%;"><input checked="" type="checkbox"/></td> <td style="width: 20%;">Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>				<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
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Date of submission of the demand <b>22 July 2004 (22.07.2004)</b>		Date of completion of this report <b>21 January 2005 (21.01.2005)</b>																									
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230		 Authorized officer Maury Audet Telephone No. 572-272-0960																									

Form PCT/IPEA/409 (cover sheet)(January 2004)

**Box No. I Basis of the report**

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ the international application as originally filed/furnished

- ☒ the description:

pages 1-27 \_\_\_\_\_ as originally filed/furnished

pages\* NONE \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* NONE \_\_\_\_\_ received by this Authority on \_\_\_\_\_

- ☒ the claims:

pages 28-30 \_\_\_\_\_ as originally filed/furnished

pages\* NONE \_\_\_\_\_ as amended (together with any statement) under Article 19

pages\* NONE \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* NONE \_\_\_\_\_ received by this Authority on \_\_\_\_\_

- ☒ the drawings:

pages 1-5 \_\_\_\_\_ as originally filed/furnished

pages\* NONE \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* NONE \_\_\_\_\_ received by this Authority on \_\_\_\_\_

- ☒ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☒ The amendments have resulted in the cancellation of:

☒ the description, pages NONE \_\_\_\_\_

☒ the claims, Nos. NONE \_\_\_\_\_

☒ the drawings, sheets/figs NONE \_\_\_\_\_

☒ the sequence listing (*specify*): NONE \_\_\_\_\_

☒ any table(s) related to the sequence listing (*specify*): NONE \_\_\_\_\_

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages \_\_\_\_\_

☐ the claims, Nos. \_\_\_\_\_

☐ the drawings, sheets/figs \_\_\_\_\_

☐ the sequence listing (*specify*): \_\_\_\_\_

☐ any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.  
PCT/US04/01468**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims <u>1-31</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>1-31</u>	YES
	Claims <u>NONE</u>	NO
Industrial Applicability (IA)	Claims <u>1-31</u>	YES
	Claims <u>NONE</u>	NO

**2. Citations and Explanations (Rule 70.7)**

Claims 1-31, as drawn to any of SEQ ID NOS: 2-3 (fragments/analogues of full 33 residue SEQ ID NO: 1) and analogues of SEQ ID NO 1 (including all the limitation of independent claim 1 from which it depends, i.e. would have to be analogues of SEQ ID NO: 2-3), SEQ ID NOS: 4-7 (also fragments/analogues of SEQ ID NO: 1), as well as methods of using any these peptides or compositions therewith, are novel under PCT Article 33(2). A sequence search of SEQ ID NOS: 1-7, did not find that the prior art of record reasonably teaches (or suggests) any of the peptides, compositions therewith, or methods using either. Only Applicant's own US 6,309,877 B1 and US Publication US 2002/0086831 A1 generally teach SEQ ID NO: 1 (recited therein as SEQ ID NO: 4) and percent identical/conservatively substituted fragments/analogues which do not (teach or reasonably suggest) the presently claimed claim 1 peptide analogues (and dependencies including all the limitations of claim 1), or compositions, or methods of using such.

Claims 1-31, as drawn to the invention above, thus also involves an inventive step under PCT Article 33(3). It would not have been obvious (routine optimization for one of ordinary skill in the art) to have arrive at the subject matter claimed in the present invention, in view of the teachings of Applicant's previous US 6,309,877 B1 or US 2002/0086831.

Claims 1-31 have industrial applicability under PCT Article 33(4) since the peptides and compositions thereof may be used in a variety of methods directed to medical conditions.

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US04/01468

## Supplemental Box Relating to Sequence Listing

## Continuation of Box No. I, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion was established on the basis of:

## a. type of material

- ☒ a sequence listing  
☐ table(s) related to the sequence listing

## b. format of material

- ☒ in written format  
☒ in computer readable form

## c. time of filing/furnishing

- ☒ contained in the international application as filed  
☒ filed together with the international application in computer readable form  
☐ furnished subsequently to this Authority for the purposes of search and/or examination  
☐ received by this Authority as an amendment\* on \_\_\_\_\_

2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments:

\* If item 4 in Box No. I applies, the listing and/or table(s) related thereto, which form part of the basis of the report, may be marked "superseded."